

Why We Are Here

- Knowledge Building
 - PM USA Quality System
 - Specific focus on Design Control
- Describe the Design Control Process
- Identify Design Control Process interface with Marketing
- Identify potential Marketing inputs and their importance in the Design Control Process
- Identify Next Steps

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What IS a Quality System?

A Quality System is the . . .

- organization structure
- responsibilities - who does what and how
- documentation - policies, procedures, records and. . .
- personnel who fulfill responsibilities using the documentation!

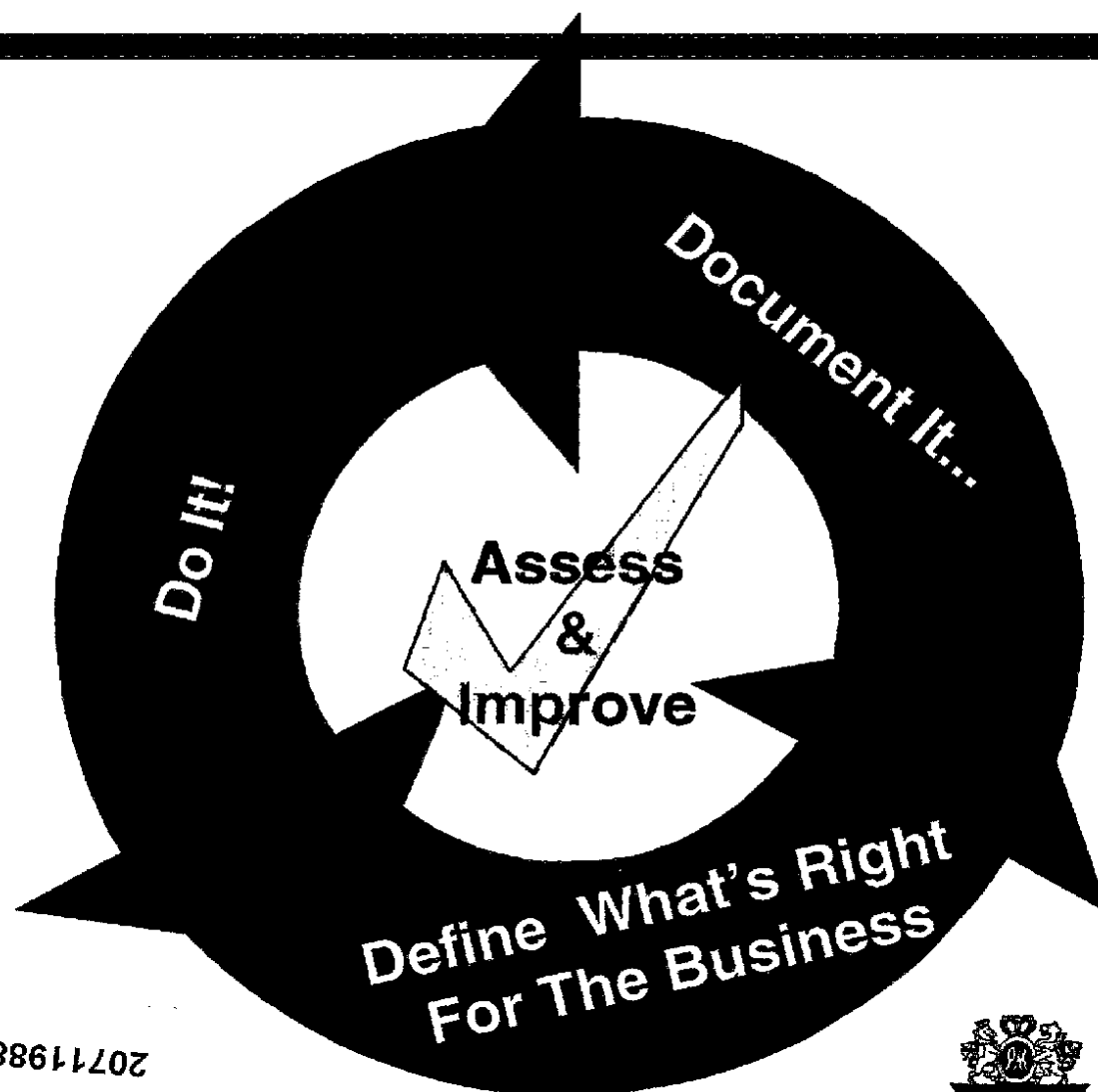
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. . . to establish a state of control that maximizes the probability of producing a correct finished product and its packaging.



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Typical Quality System Strategy



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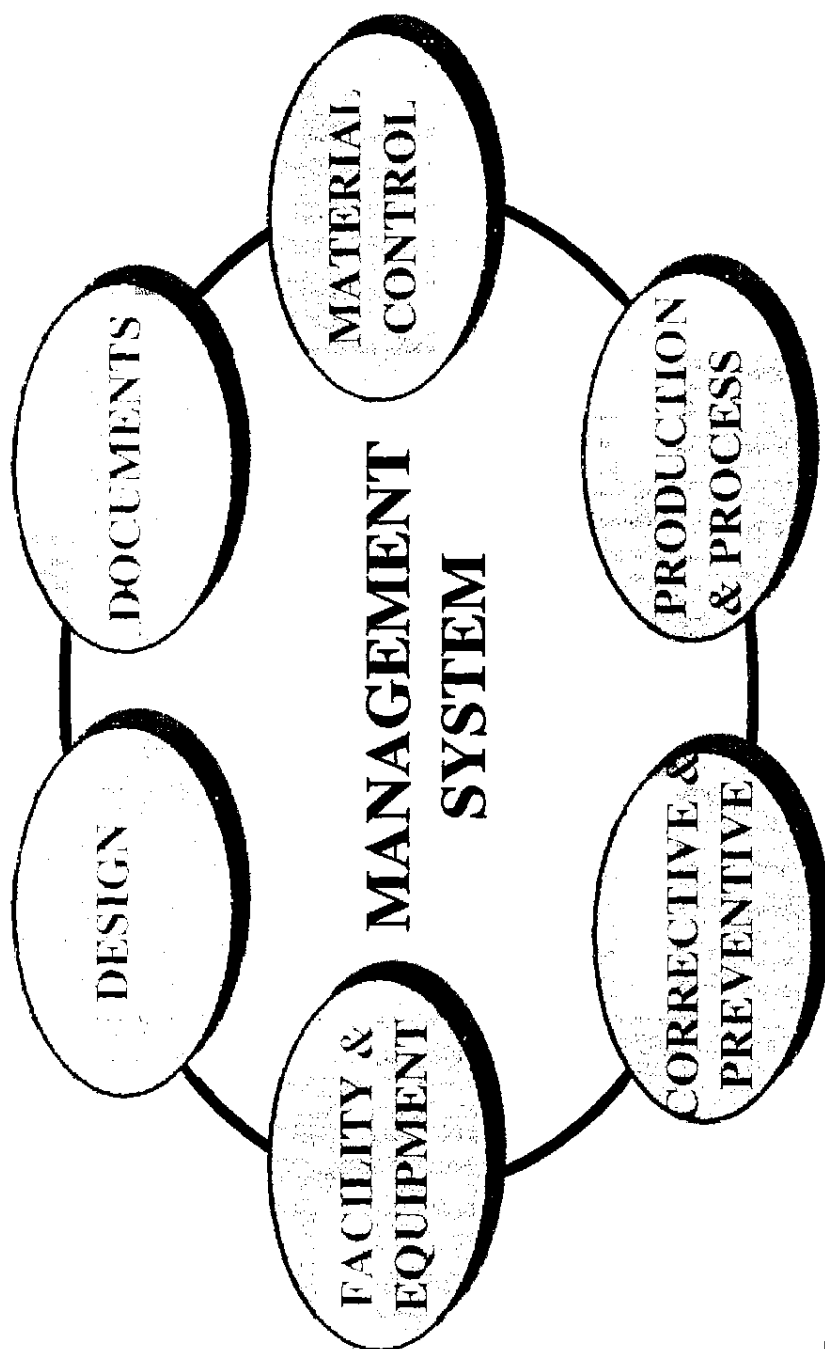
Current Situation & Guiding Assumptions

- FDA regulation of the tobacco industry as a result of Congressional action or Supreme Court decision is not certain, but is highly likely.
 - PM USA will implement a comprehensive, integrated and disciplined Quality System which meets our business needs and applicable legal and regulatory requirements.
 - This Quality system will respond to what we currently believe an appropriate industry-specific regulation would be given the assumption of future FDA regulation.
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- This Quality System will define our Quality System unless/until we receive further direction from Congress or the Supreme Court.



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PM USA Quality System Structure

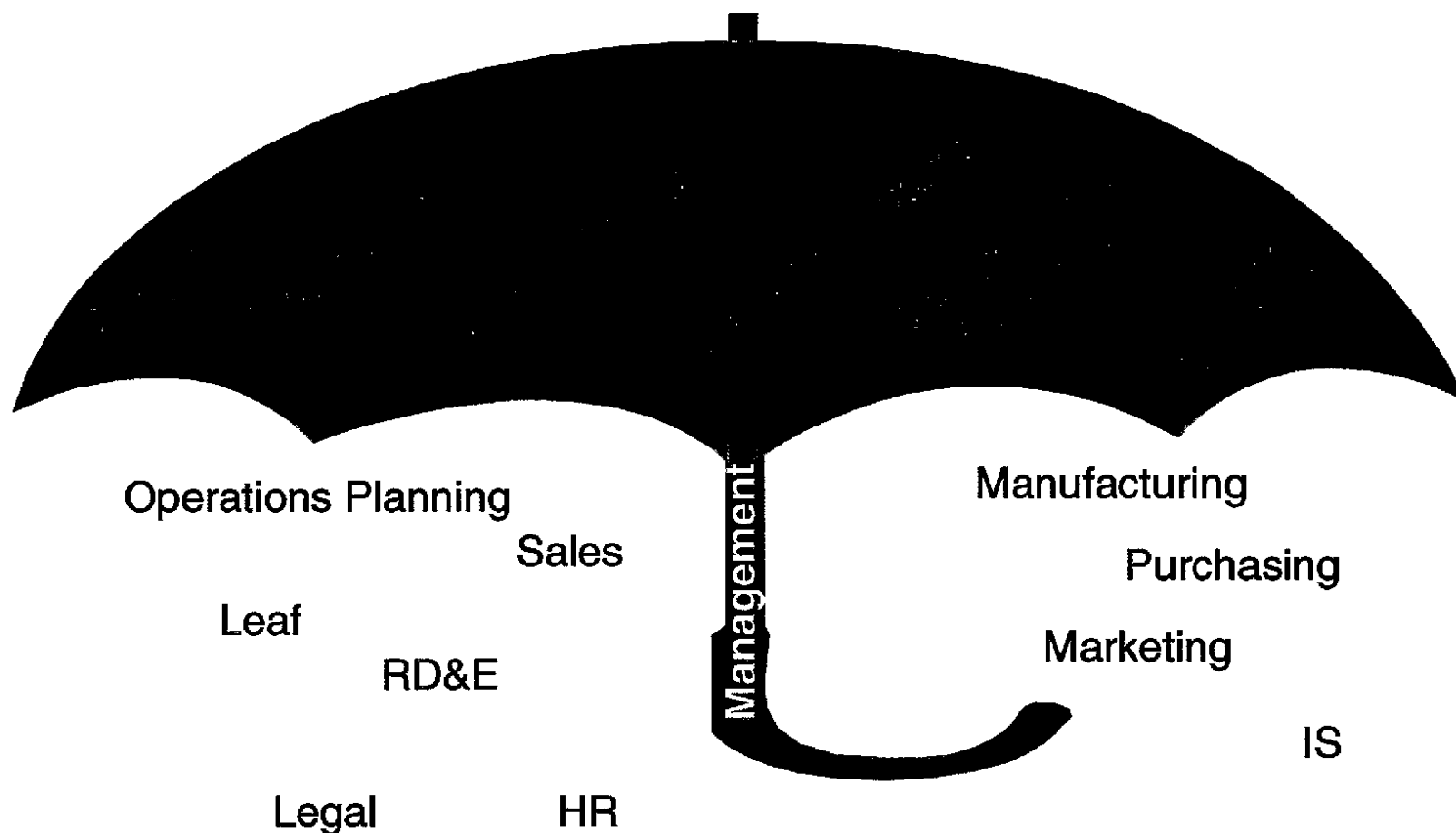


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Who is Impacted by the Quality System

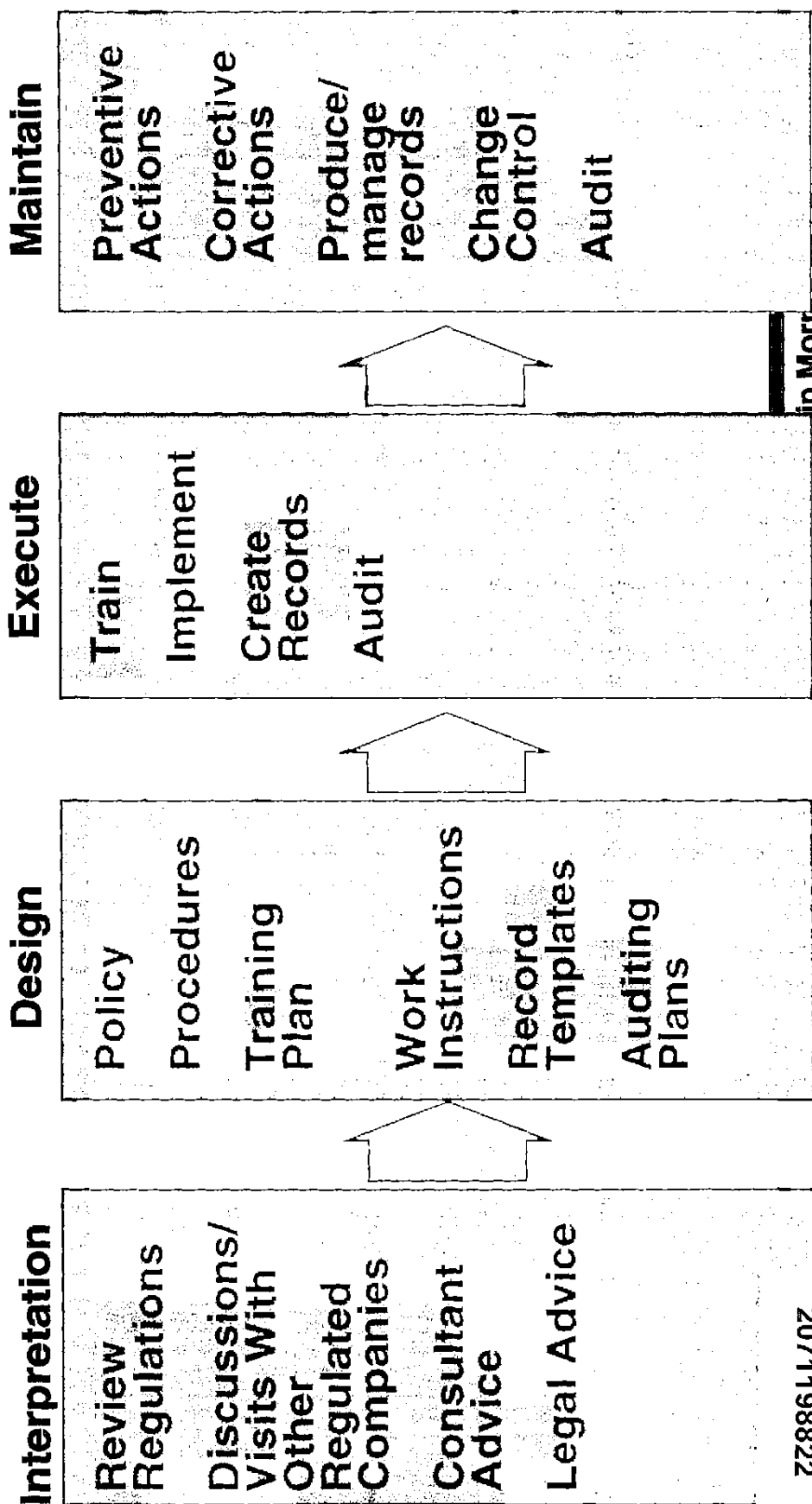


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Steps for Building the Quality System



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PM USA Quality System

Background

1998 - Gap Analysis Conducted in Operations

- By consultants acting at direction of PM counsel
- Against FDA's Quality System Regulation (QSR) for Medical Devices
- For purpose of gathering facts about PM's practices to enable counsel to provide legal advice

Operations Gap Analysis Outcomes

- Identified issues and areas of potential exposure
- Enabled PM to identify the universe of work to be done and to prioritize that work
- Project Teams formed; accountabilities assigned; schedule and milestones established
- Learning: some NY-based functions affected

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PM USA Quality System

Background

QBRI consultants performed NY scope assessment to identify functions that would be in scope of the QSR

Now need to assess current business practices in those functions against the QSR to see how they would measure up if QSR were in effect

QBRI has developed a plan for how it intends to conduct gap analysis in NY

- **NY Legal involved in scope assessment and gap analysis plan**
- **QBRI to be directed by Arthur Levine with Arnold and Porter**
- **Gap analysis is a privileged assessment**

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PM USA Quality System

Gap Analysis Plan - NY Office

Phase 1

2 weeks

Train Assigned NY Facilitators,
Gather Data and Prepare Plan

Phase 2

3 weeks

Conduct Interviews to Understand
Current Business Processes

Phase 3

4 weeks

Draft Gap Analysis Report
and Review With Functions

Phase 4

3 weeks

Appropriate Legal Review of
Draft Gap Analysis Report

Phase 5

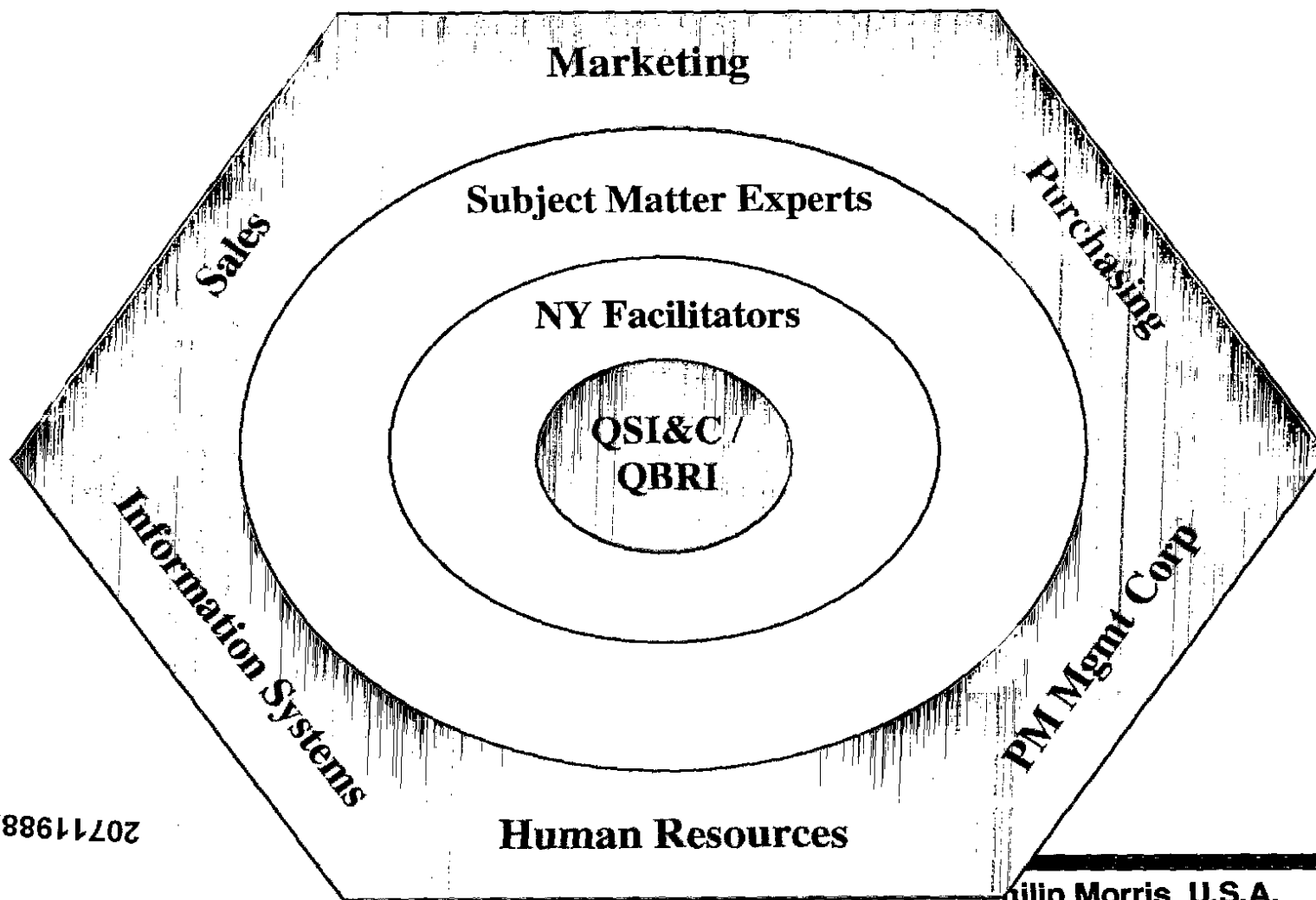
2 weeks

Final Review of Gap Analysis
Report - Develop Next Steps

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PM USA Quality System

Gap Analysis Plan - NY Office



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What is Design Control?

Documentation that provides a structure for...

... identifying, planning, verifying, validating (where necessary), and transferring finished product designs to manufacturing and...

... for ensuring all design requirements are met.

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Design Control Benefits

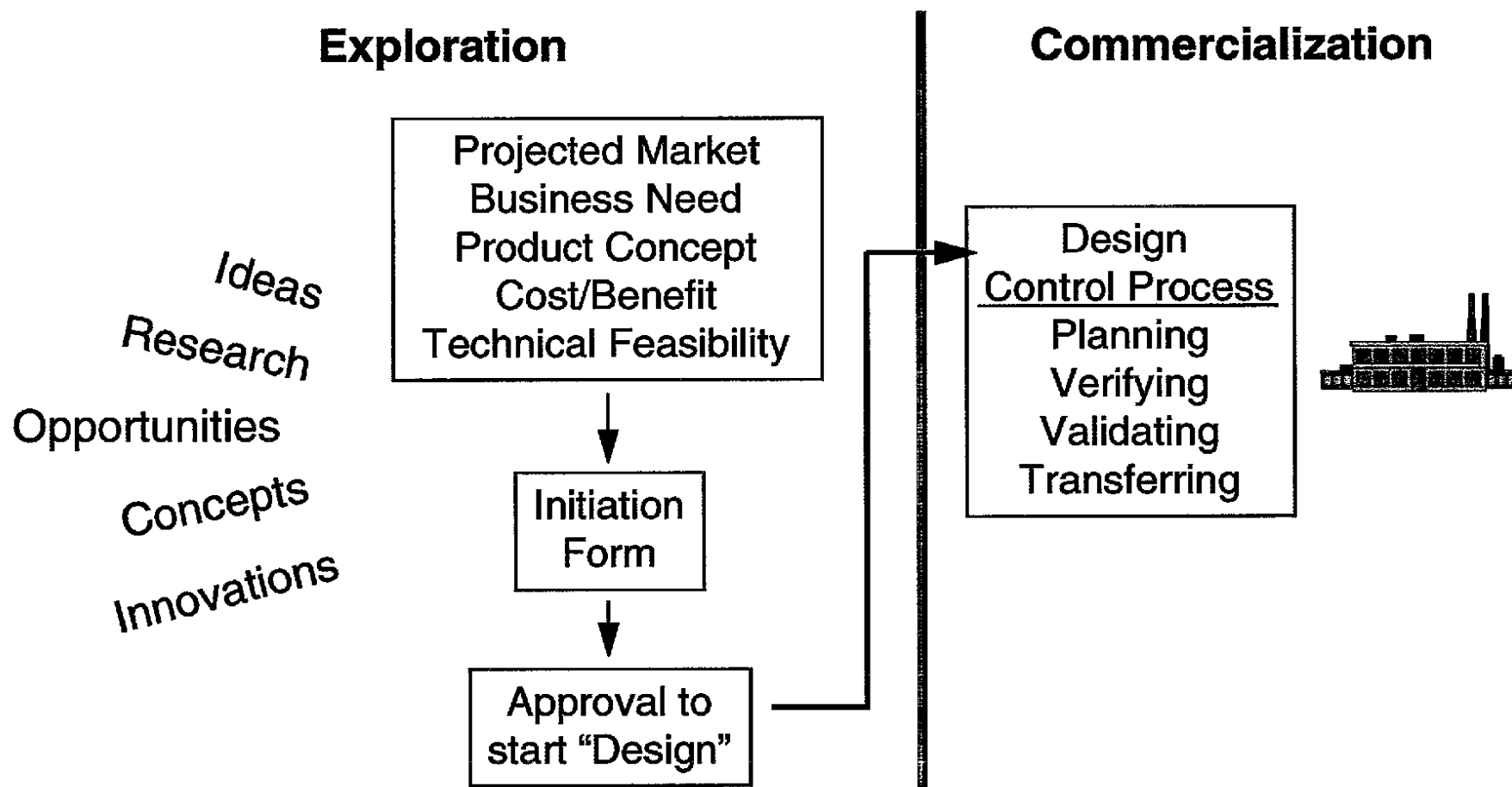
- Provides a clear, documented business process - from concept development to product development to commercialization of the finished product.
- Provides the basic planning elements for documenting and guiding design and development projects from pre-production designs to the production of the desired product.
- Establishes clear, defined accountability for design activities.

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"The Big Picture"



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What is Marketing's Role in Design Control?

Focus today is on cigarette and packaging - both new and changes ...

- Marketing contributes to the definition of consumer and market place expectations leading to a defined Product Concept
 - The Product Concept leads to the "Design Inputs" in the Design Control Process

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Marketing Input

What it could look like....

- Market Segment
- Intended Audience of Adult Smokers
- Market Share
- Volume Forecasts
- Marketing Rationale
- Proposed Timing of Launch
- Business Assumptions and Issues
- Defined Product Concept (format, physical parameters, sensory position)

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Marketing

A Cigarette Example...

Product/Process Designers

Consumer Expectations

Product Concept

Format:

LS, KS, 100
SP, HP, RCB Cork/White
FF, LTS, UL Menthol (?)
Brand Family (?)

Physicals:

Tar Level
Puff Count
Draw
Firmness

Sensory: (Internal / External)

Sensory Attributes
...like a Newport
...less harsh than a Camel

Performance Requirements

Format (examples...):

Cigarette Length
Circumference Filter Type
Filter Length Packer

Physicals (examples...):

Cigarette Firmness
Total RTD
Filter RTD
Ventilation Level

Sensory (examples...):

Tar / Puff
Menthol / Puff
Blend / Flavor System
Sensory Objectives

"Stage 0"

"Design Inputs"

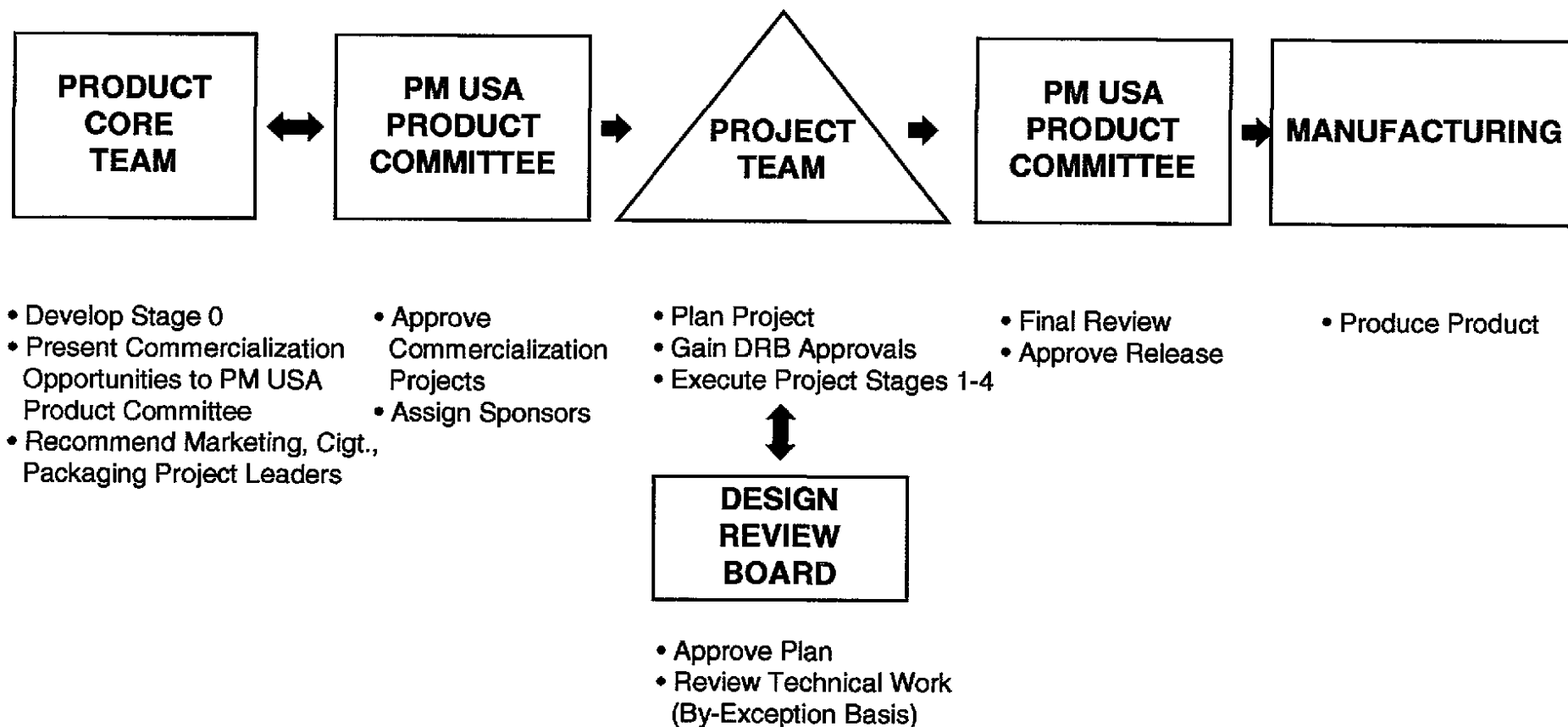
"Stage 1"

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PRODUCT PROCESS FLOW



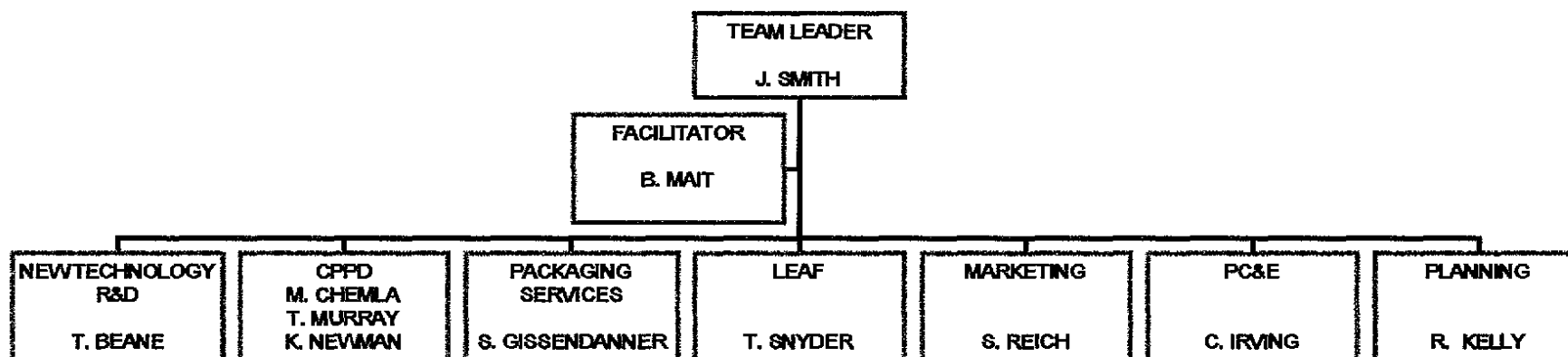
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PRODUCT CORE TEAM

STAGE 0



Role/Activities:

- Focus on Stage 0 Developments and Marketing 5 Year Plan
- Define Product Concept
- Initiate Integrated Actions to Define Feasibility
- Present Commercialization Opportunities to PM USA Product Committee for Decision
- Utilize/Develop Innovation Process

Near-Team Actions:

- Assemble Team, Finalize Charter
- Comprehensive Assessment of Current Product Activities; Develop Clear List & Assign Stages (Create L-O-R Lists)
- Review with PM USA Product Committee

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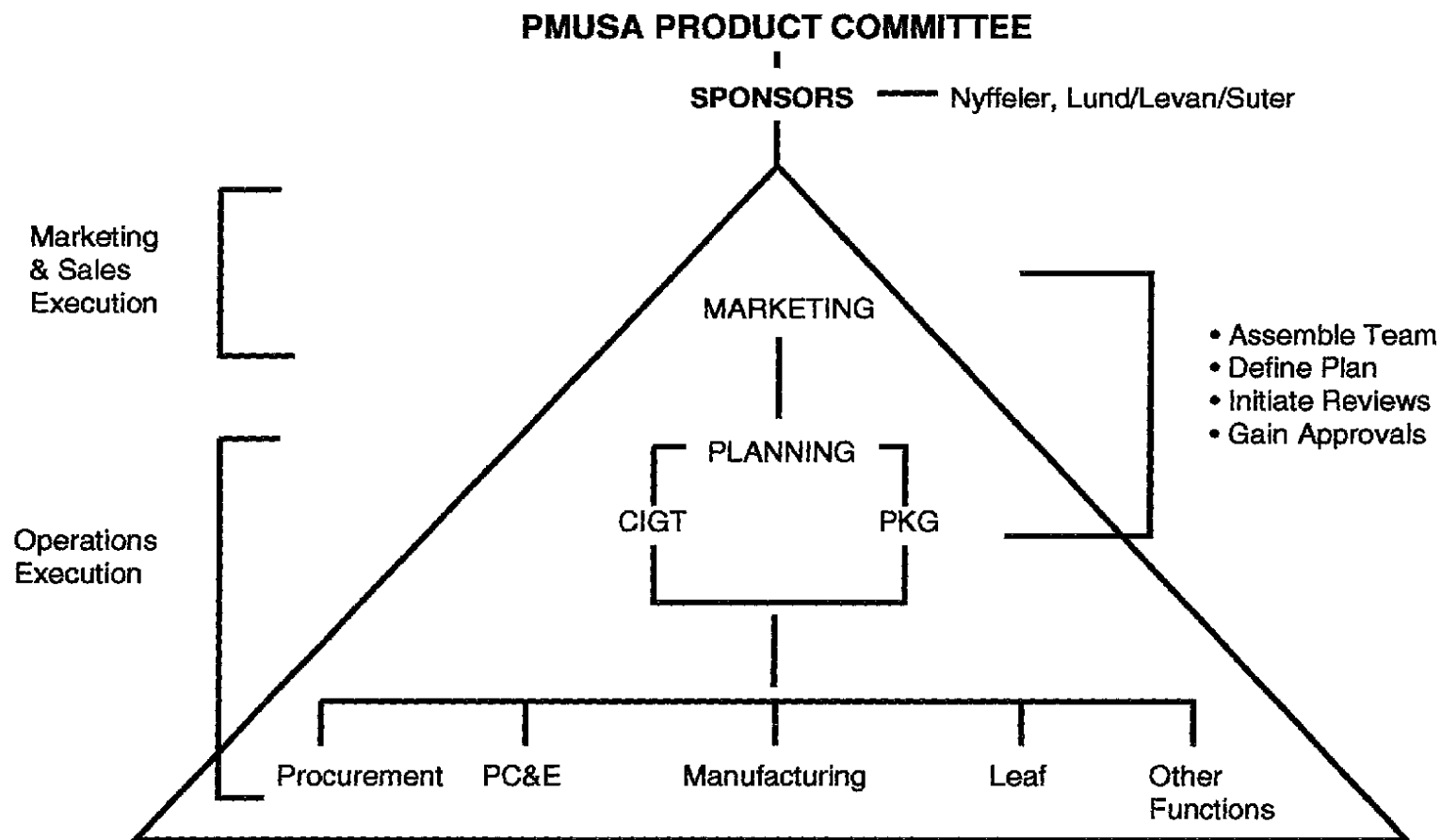
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PROJECT TEAM STRUCTURE

STAGES 1-4



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What's Next?

- Establish Marketing ~ Operations Interface to facilitate exploration and design process
- Coordinate participation with "Gap Analysis" to
 - Determine participants, roles, and design control processes
 - Once identified, define and document Procedures.

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